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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/437,726 11/09/99 STEMMER

W 02-029220US

022798 HM12/0410  
LAW OFFICES OF JONATHAN ALAN QUINE  
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EXAMINER
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SISSON, B

ART UNIT	PAPER NUMBER
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1655

DATE MAILED:

04/10/01

*13*

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

*4,6,8,10*

**Office Action Summary**

Application No.

09/437,726

Applicant(s)

STEMMER ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 6-8 10 . 20) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restrictions*

1. Claims 10-19 and 21-26 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12, received 12 March 2001.

### *Drawings*

2. The drawings remain objected to for reasons of record; see the PTO-948 that was attached to Paper No. 11.

### *Specification*

3. The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

4. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material

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incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

5. The attempt to incorporate subject matter into this application by reference to a) foreign patent documents and to non-provisional US patent applications (pages 39-40; b) to provisional applications 60/118854 (page 47) and to 60/118813 (page 48) is improper because the two provisional applications are relied upon as disclosing/enabling methods for performing stuttering and *in silico* shuffling, respectively; c) to provisional and non-issued US patent applications at page 85 for disclosing a computer system that is to be used to perform 'in silico' shuffling of character strings; d) to US patent applications (provisional and non-provisional) at page 86 for disclosing additional methods by which the claimed invention is to be practiced.

6. Only published US Patents may be relied upon via an incorporation by reference when they disclose essential subject matter. Provisional applications are not published and may not be incorporated by reference when they disclose essential subject matter. Similarly, journal articles and foreign patent documents may not be relied upon via an incorporation by reference when they disclose essential subject matter.

7. The use of the trademarks TWEEN, NONIDET (NP-40) and TRITON have been noted in this application. They should be capitalized wherever they appear and be accompanied by their generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *In re Wands*, 8 USPQ2d 1400 (CAFC 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

***The Quantity of Experimentation Necessary***

The quantity of experimentation need is great, on the order of several man-years and then with little, if any, reasonable expectation of success.

***The Amount of Direction or Guidance Provided and the Presence or Absence of Working***

***Examples***

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The amount of guidance provided is severely limited and then the guidance is prophetic and is achieved through numerous improper incorporations by reference to either foreign patent documents, provisional and non-provisional patent applications.

*The Nature of the Invention*

The claimed invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

*The State of the Prior Art*

The state of the prior art is one where much interest exists in the identification of mutant genes that encode enzymes with enhanced properties. In so far as the prior art teaching the identification of such mutated Rubisco enzymes, there is a very limited development in the relevant art.

*The Relative Skill of Those in the Art*

The relative skill of those in the art that is most closely associated with the claimed invention is high, on par with those that hold a Ph.D. in biochemistry.

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*The Breadth of Scope of the Claims*

The claims are drawn to a method of producing and identifying a genus of polynucleotides that encode an “enhanced Rubisco protein having Rubisco catalytic activity.” As presently worded, the claimed method is to be applicable to the modification of any of the genus of parental Rubisco sequences. At page 65 of the specification it is disclosed the invention is to encompass such “enhanced” sequences that have been derived from the Rubisco sequence as found in “corn, rice, triticale, rye, cotton, soybeans, wheat, oats, barley, millet, sunflower, canola, peas, beans, peanuts, yam beans, cowpeas, velvet beans, clover, alfalfa, lupine, lotus, sweet clover, wisteria, sweetpea and nut plants (e.g., walnut, pecan, etc.).” The specification does not set forth the parental sequences for any one of these plants, yet the method requires the shuffling of these and any other parental sequence. It is apparent that applicant is relying upon those of skill in the art to first develop the starting materials, which here is the parental sequence, as well as the conditions under which they are to be “shuffled.” Such shifting of the burden of full and complete enablement is improper as it unfairly places an undue burden on the public. It is the specification, not the public, that is to fully enable the claimed invention. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

“ ‘[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.’ *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) (‘[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.’). ”

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“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that ‘a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

“It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (emphasis added)

For the above reasons, and in the absence of convincing evidence to the contrary, the invention of claims 1-9 and 20 has not been found to be enabled by the instant specification and as such, said claims have been rejected under 35 USC 112, first paragraph.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-9 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.



11. The term "enhanced" in claim 1 is a relative term that renders the claim indefinite. The term "enhanced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2-9 and 20, which depend from claim 1 fail to overcome this issue and are similarly rejected

12. The term "significantly lower" in claim 1 is a relative term that renders the claim indefinite. The term "significantly lower" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2-9 and 20, which depend from claim 1, fail to overcome this issue and are similarly rejected.

13. The term "low co<sub>2</sub>/o<sub>2</sub> ratios" in claim 1 is a relative term that renders the claim indefinite. The term "low co<sub>2</sub>/o<sub>2</sub> ratios" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2-9 and 20, which depend from claim 1, fail to overcome this issue and are similarly rejected.

14. The term "significantly lower K<sub>m</sub> for CO<sub>2</sub>" in claims 1 and 4 is a relative term that renders the claims indefinite. The term "significantly lower K<sub>m</sub> for CO<sub>2</sub>" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2-9 and 20, which depend from claim 1, fail to overcome this issue and are similarly rejected.

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15. The term "significantly higher  $K_m$  for  $O_2$ " in claim 3 is a relative term that renders the claim indefinite. The term "significantly higher  $K_m$  for  $O_2$ " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

16. Claims 1-9 and 20 are confusing with respect to the phrase "the Rubisco activity encoded by the parental sequence(s)." Are the "parental sequence(s)" nucleotide or amino acid? If they are nucleotide, then added clarification is needed as to how a nucleotide sequence encodes "activity." Seemingly, the nucleotide would encode a protein, where as here, it could be an enzyme that demonstrates a certain level of activity.

17. Claim 20 recites the limitation "the one or more first Calvin or Krebs cycle enzyme" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 20 recites the limitation "the homologue thereof" in line 2. There is insufficient antecedent basis for this limitation in the claim.

19. Claim 20 recites the limitation "the one or more homologous first nucleic acid encodes a Rubisco enzyme" in line 2, bridging to line 3. There is insufficient antecedent basis for this limitation in the claim.

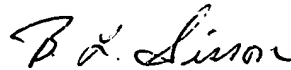
### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson  
Primary Examiner  
Art Unit 1655

BLS  
April 9, 2001